A SYSTEMATIC EVALUATION OF A NEWBORN SCREENING PROGRAM FOR SICKLE CELL DISEASE IN SOUTHERN GUJARAT, INDIA

by

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Abstract

Introduction: Newborn screening (NBS) is an important public health measure aimed at early identification and management of affected newborns. Sickle Cell Disease (SCD), with an estimated 5,200 live births every year, is a major public health problem in India. Pre-symptomatic diagnosis, institution of pneumococcal prophylaxis and provision of comprehensive care offer the possibility of prevention of complications and improving outcome of SCD.

In India, SCD is highly prevalent among autochthonous ethnic groups called scheduled tribes. These communities also have a high prevalence of extreme socio-economic disadvantage. The population of scheduled tribes in the western state of Gujarat exceeds 14 million individuals. Since 2008 NBS for SCD has been piloted in Valsad and nearby areas. NBS is currently being expanded to other tribal districts in the state. Evaluation of the NBS program is essential for guiding the implementation of NBS in Gujarat and elsewhere.

Objectives: To evaluate the pre-analytical, analytical, post-analytical, and organizational aspects of the pilot NBS Program for SCD in Valsad, Gujarat, India.

Methods: Using a standardized Performance Evaluation and Assessment Scheme (PEAS) for NBS modified for developing countries we performed systematic evaluation of the pre-analytical, analytical, post-analytical, and organizational aspects of the pilot NBS Program for SCD in Valsad.

Results: Since the inception of NBS in 2008 more than 3500 newborns have been screened using High Pressure Liquid Chromatography and iso-electric focusing with confirmation by molecular

methods. Individuals identified with SCD receive comprehensive care and families of those with sickle cell trait receive genetic counseling. Using modified PEAS methodology the pre-analytical, analytical and post analytical aspects of the NBS program received a score of 37/46 meeting 80.4% of standards. The organizational domains received a score of 32/34 meeting 94% of standards.

Public Health Implications: There has been a serious lack of information on the feasibility of newborn screening and comprehensive care for hemoglobinopathies in a developing country. These data demonstrate the feasibility of implementing NBS for SCD among communities facing extreme social disadvantage in a developing country. They provide the framework for implementation and evaluation of NBS programs for SCD in developing countries.

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1.0 INTRODUCTION

Newborn screening is recognized internationally as an essential, preventive public health program for early identification of disorders in newborns that can affect their long term health. Early detection, diagnosis, and treatment of certain genetic, metabolic, or infectious congenital disorders can lead to significant reductions of death, disease, and associated disabilities.(1) Newborn screening is now present in most countries in Europe, Australia, New Zealand, the Philippines and other countries around the world but the diseases screened and the methods used vary from country to country. With the completion of the Human Genome project, the expansion of genetic knowledge and technology into the public health arena has risen and has presented opportunities for understanding and promoting health, lowering mortality and morbidity rates, and preventing diseases.(2)

Initiation of newborn screening in developing countries has been slow because of a variety of factors. Developing countries face challenges related to poor economies, unstable governments, unique cultures, geographic extremes, and different public health priorities.(3) The various languages and dialects present in developing countries also pose a difficulty since it can cause communication problems. This impedes researchers and experts in newborn screening from developed programs from communicating and advising individuals in countries with developing programs.(3) Regardless, newborn screening is becoming a priority in many developing countries around the world.

Historically, the initiative in creating a newborn screening program has come from individuals and groups that are interested and concerned about improving the lives of newborns and the well-being of families. However, in order for a successful and sustainable newborn screening program, the newborn screening system needs to intersect with government public health activities. Success in developing and institutionalizing newborn screening has resulted from the continued efforts of dedicated leaders willing to gain proficiency in newborn screening medical and laboratory science to overcome political, cultural, and economic challenges.(3)

While over fifty countries around the world have implemented some sort of genetic screening system, India, with the second largest population in the world, still has no national newborn screening program. A few private laboratories offer screening services but those services are only accessible to those that can afford the costs which the majority of the population in a country like India cannot. A few states have taken the initiative to establish pilot screening programs but until the national government takes a stance and invests in a screening program there will be difficulties in establishing a sustainable program.

1.1 PUBLIC HEALTH RELEVANCE

The Centers for Disease Control and Prevention (CDC) established the Office of Public Health Genomics aimed to integrate genomics into public health research, policy and programs, which could improve interventions designed to prevent and control the country's leading chronic, infections, environmental and occupational diseases.(1) Newborn screening, an example of a program in the field of public health genomics, in the United States has been extremely successful, preventing thousands of premature illnesses and deaths per year. Many of the

conditions identified through newborn screening are metabolic disorders, once identified these disorders can be treated before severe symptoms such as mental retardation and developmental delays appear and become permanent.

Approximately one out of every 1,500 babies will be born with one of the disorders detectable through newborn screening.(2) Less than ten percent of babies born in the US currently get comprehensive screening for all metabolic, endocrine and hematological disorders already detectable through existing routine newborn screening programs and six babies are born every day in the United States alone that have disorders detectable through newborn screening but go undetected because they are not screened.(1, 2) Conditions identified through newborn screening can lead to disability or death without proper intervention and management. Screening programs collect more blood samples than are necessary to complete screening tests in most infants. If given permission the extra samples can also be used for the development of new methods and tests that can help identify even more conditions.

In order to include a certain condition in a newborn screening program, there are certain prerequisites that should be met prior, in order to achieve optimal results:

1.1.1 in regard to the condition, it should represent a relevant public health problem, with natural history well-known and the diagnosis should be possible in a pre-symptomatic stage (4)

1.1.2 in regard to the test, it should be safe, reliable, inexpensive, cost-effective, with a good specificity and sensibility, represent or cause no physical or psychological harm, and it should allow to quality control measures (4)

1.1.3 in regard to the management, it should be effective, and be associated with a better prognosis in the case it's started in an early stage of the

disease (4)

For conditions for which not all criteria are met, for example, the existence of an effective management that changes the natural course of the condition, the inclusion of the condition in a screening program is questionable.(4)

Newborn screening provides a quick and inexpensive way to identify numerous conditions that can be treated effectively from birth. These conditions if left untreated can cause problems and symptoms that will require lifelong care and management. The quality of life is drastically higher for affected individuals that are treated from birth compared to individuals that receive care and treatment a few months into life. (1, 2)

1.2 INDIA: GENERAL INFORMATION

India has a universal health care system run by the local (state or territorial) governments. Government hospitals provide treatment at taxpayer expense. The Constitution charges every state with "raise of levels of nutrition and the standard living of its people and the improvement of public health as among its primary duties."(5) Most essential drugs are offered free of charge in these hospitals.(1) However, the government sector is understaffed and under-financed. The very poor standards at these state-run hospital force many people to visit private medical practitioners or seek complex treatment and health services outside the country.

The National Health Policy approved by the Indian parliament in 1983, and updated in 2002 failed to mention the importance of implementing a genetic screening system in India.(6) Whereas, 52 countries across the world (using Dried Blood Spot as a sample) are currently implementing some form of newborn screening mandatory at the national level.(3) Neonates are not screened in India partly because the health policies have typically targeted mortality and

infectious morbidities but not disabilities. Their health policies have been successful in reducing infant mortality rates, but the net effect of these gains has been offset by an increase in disability, a result due to lack of an early diagnosis.(7)

1.2.1 Current State of Affairs

While the federal government of India has yet to implement a mandatory screening program for newborn babies, some state governments have already carried matters into their hands and have started implementing a mandatory NBS program within their state.(3) For the past two years the state government of Goa in western India screens every newborn in their health care facilities for 50 disorders.(8) Few laboratories and hospitals in India are only offering this as an option to the parents but with growing awareness of the importance of NBS, the parents are now voluntarily opting for comprehensive genetic screening from private laboratories and paying additional charges for NBS service.(7) Influences from developed countries and a sharp increase in Internet usage in the Indian population are mainly responsible for the increase in awareness of NBS in India. There is one lab in India that offers screening of more than 100 disorders, primarily by urine. Urine sampling is not the accepted NBS paradigm worldwide, despite the higher accuracy and sensitivity of the procedure.(8) The premium cost is one of the reasons it is not available to public at large through the national government establishments. The sample accepted worldwide for Newborn Screening remains Dried Blood Spot (DBS) and after indication of a disorder, the urine sample is recalled for confirmation. (1, 3, 8) The obvious negative for this procedure is loss of time for the newborn at risk. Mostly the NBS program in the world uses DBS, though the paradigm is slated for a change as the science evolves.

One of the prerequisites for a screening program is the availability of epidemiological data regarding disease burden. However, genetics being a combination of high end research plus information technology requires an ultramodern facility as well as a network of specialized clinicians to make parents aware and also treat the positive, implementing such an expensive and inclusive screening has been overlooked and delayed in India.

1.2.2 Pilot Studies for Newborn Screening

It may not be viable economically and ethically to screen for a complete range of disorders for which diagnostics modalities are available. Specific criteria that serve as a template to decide what disorders to include in the screening at a national platform are: (1) biochemically well identified disorder; (2) known incidence in the population; (3) disorder associated with significant morbidity and mortality; (4) effective treatment available; (5) period before which intervention improves outcome; and (6) availability of an ethical, safe, simple and robust screening test. The developed countries have prioritized the diseases according to the incidence. For most developed countries, initial targets for screening were phenylketonuria and congenital hypothyroidism, but now have expanded to other genetic disorders like congenital adrenal hyperplasia (CAH) , cystic fibrosis, galactosemia, G6PD deficiency, biotinidase deficiency, hemoglobinopathies e.g. Sickle Cell Disease (SCD), and non-genetic targets such as hearing and intrauterine infections, especially toxoplasmosis.(1, 3)

The state of Gujarat in India is the first state to implement a program for screening and treatment of hemoglobinopathies. Hemoglobinopathies including Thalassemia with an estimated 10,000 live births each year and sickle cell disease (SCD) with an estimated 5,200 live births each year is a major public health crisis in India. The objective for this newborn screening

program is to combine the establishment of high laboratory screening methods, strategies for follow-up, standardized clinical care, information technology for tracking patient care and socio-behavioral studies to determine the feasibility, efficacy and acceptability of a newborn screening and follow up program for hemoglobinopathies.(7)

2.0 PERFORMANCE EVALUATION ASSESSMENT SCHEME (PEAS)

Newborn screening consists of 6 components: education, screening, follow-up, diagnosis, management and evaluation. It is commonly a system that functions within local geographic, economic, and political constraints, and seeks to integrate sample collection, laboratory analysis, follow-up diagnosis and treatment.(9) The Maternal and Child Health Bureau within the United States Health Resources and Services Administration provided funding to develop realistic quality assessment indicators for assessing and improving the quality of NBS systems.(10) This resulted in the creation of an evaluation assessment scheme entitled the Performance Evaluation Assessment Scheme (PEAS). PEAS is a comprehensive listing of quality indicators for system self-assessment. The U.S. PEAS emphasized improved operation of screening and follow-up through a system of self-evaluation and quality assurance.(3, 11)The development project included an oversight committee of knowledgeable individuals experienced in working with NBS systems (including consumers) to: (a) better define the goals of the project; (b) outline the activities necessary to complete the goals and the project; (c) review and develop working group charges and challenges; (d) develop a timeline for project completion; (e) review and develop a project evaluation plan; and (f) provide ongoing project oversight.(3, 11) The evaluation assessment is divided into four stages: pre-analytical (education and screening), analytical (laboratory testing), post-analytical (reporting, short-term follow-up/tracking, diagnosis,

treatment/management, ancillary services, and outcome evaluation), and organizational. (10) These stages need to work effectively to ensure a quality newborn screening (NBS) program.

3.0 SPECIFIC AIM

The aim of this project was to determine the steps needed to evaluate the pre-analytical, analytical, post-analytical, & organizational stages of a pilot Newborn Screening Program for SCD and other hemoglobinopathies in the tribal districts of Gujarat and identify gaps and subsequent solutions that need to be addressed in the pilot screening program to increase effectiveness.

4.0 METHODS

The original PEAS model was developed in the United States which has a more complex and comprehensive newborn screening program. Previously, the PEAS model was used to evaluate the Philippine newborn screening program.(11) The framework of evaluating the Philippine newborn screening program was used as a model when creating measurable indicators for inclusion in the Gujarat PEAS. Collaborators from the U.S., the Valsad Raktadan Kendra (site of the newborn screening program) and the Indian Council of Medical Research in Mumbai, India were involved in the PEAS development process. Both the U.S. and Philippine process were reviewed along with the indicators developed. If appropriate, a particular indicator was then added to the Gujarat PEAS evaluation. Due to the small infrastructure of the program in Gujarat, many of the evaluation indicators were modified to meet the modest demands of the local system. These modified indicators where then compiled into a list to create the final PEAS document. These modified standards were distributed to the screening facility and a team member and director of the screening program reviewed the screening facility in accordance with these guidelines.(11) The individuals reviewed records, action plans and other relevant information, discussed program issues and goals, solutions and current state of progress in program implementation.(10, 11)

The PEAS scoring system, adopted from the Philippine evaluation, for the newborn screening facility, Figure 1, was qualitative with eight qualitative areas of interest assessing

overall performance.(10, 11) Each of these areas were characterized with one or more indicators for which the response could be ‘yes,’ ‘no,’ or ‘maybe.’ The scoring for the newborn screening program administration included quantitative evaluation of five groups of indicators covering operational structure, plan of action, systems in place, health promotion plan and a contingency plan as shown in Figure 2.(10, 11) For each area of interest, there were several indicators and each could be assessed as yes (in place and monitored), no (not in place), or ‘in progress.’ Points were given for yes = 1 and no = 0 and items in progress were not given points.(10, 11) Results of PEAS scores were summarized and overall performance for the pilot program was assessed. Future direction and plans for improvement were discussed.

5.0 RESULTS & DISCUSSION

Figures 1 and 2 show the results of the PEAS scoring. Figure 1 represents the evaluation of the pre-analytical, analytical and post-analytical stages. Of the indicators assessed in this evaluation, the pilot newborn screening met 37/46 (80.4%) of standards. Figure 2 represents the evaluation of the organizational component of the newborn screening program. For this portion of the evaluation, 32/34 (94%) of standards were met.

Initiation of newborn screening in developing countries has been slow because of a variety of factors. Developing countries face challenges related to poor economies, unstable governments, unique cultures, geographic extremes, and different public health priorities.(3) The various languages and dialects present in developing countries also pose a difficulty since it can cause communication problems. This impedes researchers and experts in newborn screening from developed programs from communicating and advising individuals in countries with developing programs. Regardless, newborn screening is becoming a priority in many developing countries around the world.

The state government of Goa introduced a universal newborn screening program for a period of four years beginning in 2008. This program was the first to screen every newborn in the state for 50+ genetic conditions in India.(8) The states of Chhattisgarh, Andhra Pradesh, and Gujarat have also all implemented pilot newborn screenings for various conditions, however, no

formal evaluation have been performed to assess and identify gaps, solutions and areas of improvement.(7, 8, 12-15)

The comprehensive newborn screening system performance evaluation scheme (PEAS) published by Therrell et al (10) has been successfully adapted to evaluate newborn screening programs in the developing world.(11) Using these standards we present the results of our self-assessment of newborn screening system and have identified areas of strengths as well as barriers that have to be overcome for future implementation of newborn screening programs in India.

This evaluation serves as a baseline to identify gaps in the program that need to be addressed as the program becomes integrated into the state health system. As a result of the assessment a formalized action plan clearly indicating the targets and goals of the newborn screening program was created and a mechanism for routine monitoring and continual review of program implementation were developed.

FACILITIES INDICATOR	COMPLETION STATUS
A. **Existence of an Effective Newborn Screening Team**	
1. The health facility has a working NBS Team	**Yes**
2. The composition of the NBS Team is appropriate	**Yes**
3. All NBS Team members underwent NBS orientation/training	**Yes**
4. All NBS Team members are well-informed about newborn screening	**Yes**
5. The role of each NBS Team member is clearly defined	**Yes**
6. Every NBS Team member effectively performs his/her tasks	**Yes**
B. **Existence of a newborn screening program Action Plan in the health facility**	
1. The health facility has a newborn screening plan of action	**No**
2. The newborn screening action plan for the year is being implemented	**No**
3. Clear targets indicated in the action plan	**No**
4. The NBS action plan targets are being met	**No**
5. The health facility has an advocacy program	**Yes**
6. A newborn screening advocacy program is being implemented	**Yes**
C. **Implementation of NBS program**	
1. Motivating parents to have their newborns screened is never a problem	**Yes**
2. Most patients were motivated to have NBS service once they know about it	**Yes**
3. Collecting the NBS blood sample is done routinely and skillfully	**Yes**
4. A logbook of patients is maintained	**Yes**
5. A quality check of samples is being made prior to submission	**Yes**
6. Samples are promptly sent to the NSC	**Yes**
7. Samples sent to the NSC have never been rejected due to contamination or insufficiency	**Yes**
8. The courier service is prompt and efficient for pick-up of samples	**Yes**
9. There have been no problems in the service of the courier	**Yes**
10. Normal results received are relayed to the parents immediately	**No**
11. Abnormal results received are relayed to the parents immediately	**Yes**
12. The health facility has a well-defined system in recalling patients	**Yes**
13. The health facility can easily recall patients	**Yes**
14. The health facility can easily refer, manage and recall positive cases	**Yes**
D. **Awareness on availability of NBS service in the health facility**	
1. All personnel in the health facility are aware that we offer NBS services	**Yes**
E. **Adequacy of NBS Education materials**	
1. NBS posters posted in strategic places in the health facility	**Yes**
2. NBS brochures are available for target patients	**Yes**
F. **Administrative support for NBS implementation**	
1. Administrative support is given to the NBS Team	**Yes**
2. Administration provides financial support to ensure smooth implementation of NBS	**Yes**
G. **Existence of a Monitoring and Evaluating mechanism on the Implementation of NBS**	
1. The health facility administration has a quarterly assessment of the implementation of NBS	**No**
2. The NBS team conducts a quarterly assessment to review implementation and problems encountered	**No**
3. The health facility administration conducts an annual assessment of the implementation of the NBS	**No**
4. The NBS team conducts an annual assessment to review implementation and problems encountered	**No**
H. **Transactions with the Newborn Screening Center**	
1. The health facility is using the Purchase Order system	**Yes**
2. Purchase orders are processed and received within 7 working days	**Yes**
3. Supplies received from the NBS center are always complete and in good condition	**Yes**
4. Rejected samples are immediately communicated for the immediate recall of patients	**Yes**
5. Billing statements received from the are always accurate	**Yes**
6. Health facility is able to pay the purchase request within the 45-day payment period	**Yes**
7. Normal results are relayed within 7 working days by the NSC through email, phone or fax	**Yes**
8. Abnormal results are relayed promptly for patient recall	**Yes**
9. Monthly summary of results is generated regularly	**Yes**
10. Inquiries are immediately entertained and handled	**Yes**
11. Concerns are given prompt action	**Yes**

Figure 1: PEAS Indicators for the Newborn Screening Facilities

ADMINISTRATIVE INDICATOR	COMPLETION STATUS
I. **Operational Structure**	
A. Staffing	
1. Sufficient staff are available to administer the program composed of:	**Yes**
i. CHD Program Coordinator	**Yes**
ii. Medical/Nurse Coordinator/s	**Yes**
iii. Alternate staff from the CHD for contingencies	**Yes**
2. Written defined roles and responsibilities	**Yes**
B. Personnel Training	
1. A personnel training plan/program exists	**Yes**
2. The training plan for new personnel includes (in writing) instruction in:	
i. Administrative policies and procedures	**No**
ii. Program operation (including all systems components)	**No**
iii. Technical procedures (Heel Prick Method, Specimen checking, Recall & Follow-up Protocols, Safety Measures)	**Yes**
iv. Available resources (local, regional, national, international)	**Yes**
v. Continuing education (attendance at conferences at least annually)	**Yes**
C. Personnel Competency	
1. Competency assessment includes:	
i. Documentation of sufficient educational background (doctor or nurse)	**Yes**
ii. Documentation of appropriate experience (heel prick method)	**Yes**
iii. Documentation of continuing education/certification	**Yes**
iv. Performance competency evaluation for each employee at least annually	**Yes**
II. **Plan of Action (Work and Financial Plan)**	
1. Action plan for year containing objectives, targets, activities	**Yes**
2. Accomplishment report for previous year	**Yes**
III. **Systems in Place**	
1. Financing schemes for NBS activities	**Yes**
2. Information system	
i. Updated directory of all health facilities	**Yes**
ii. Statistics (Number of deliveries, newborns screened, positive screens, confirmed positive, lost to follow-up, unsatisfactory samples, dissents, and list of health facilities indicating status of implementation	**Yes**
iii. Reporting system/Tracking and frequency of reports	**Yes**
iv. Directory of specialists for referral and case management	**Yes**
3. Network and linkages	
i. Established network for advocacy, recall of patients and financing	**Yes**
ii. Referral system (written protocol)	**Yes**
4. Monitoring scheme	
i. Monitoring plan containing Health Facilities to be visited and frequency of visit	**Yes**
ii. Monitoring checklist	**Yes**
iii. Documentation of monitoring conducted	**Yes**
5. Documentation of planning and consultative meetings.	**Yes**
6. Annual program implementation review with documentation	**Yes**
7. Recall, follow-up, referral and management protocols (written)	**Yes**
IV. **Health promotion plan**	
A. Communication Plan	
1. A comprehensive, written communication plan prepared with input from stakeholders	**Yes**
2. IEC/reference materials available (Manual of Operations, Posters, Brochures, CDs and Books on Guide for Primary Physician and NBS Coordinators, Flipcharts, IEC materials and DOH Issuances)	**Yes**
3. A method for periodic review and update of the plan	**Yes**
V. **Contingency Plan**	
1. Addressing manpower turnover	**Yes**
2. Other issues	**Yes**

Figure 2: Performance Evaluation & Assessment Scheme Indicators for the Newborn Screening Program Administration

6.0 CONCLUSION

The information gained from this evaluation provides information that is essential to improve the quality of the newborn screening program. As newborn screening programs are developed and expanded it is important that there are standards to follow and PEAS serves as a quality self-assessment tool. There is a lack of information on the feasibility of newborn screening and comprehensive care for hemoglobinopathies in a developing country. Using PEAS as a standard, multiple evaluations, spanning a number of years, will provide important feedback to the advancement of the newborn screening program in Gujarat. This information will also be important in guiding other developing newborn screening programs in India that face the same challenges.

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